



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
7200 Lake Ellenor Drive  
Orlando, FL 32809

M 863M

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Ref: FDA Sample No. 3109434  
Customs Entry: Informal  
Product: Fresh Callaloo

WARNING LETTER

FLA-97-44

April 28, 1997

Mr. Harbie Fletcher  
President, West Indies Produce, Inc.  
8635 N.W. 68th Street  
Miami, Florida 33166

Dear Mr. Fletcher:

The Food and Drug Administration (FDA) attempted to examine a shipment of fresh callaloo offered for entry into the United States by your firm on February 26, 1997, under the above referenced entry number, and found that the shipment was not held intact for FDA examination. Regulation, Title 21, Code of Federal Regulations (CFR), Part 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U. S. Customs Service (Customs) to require formal entries on all future shipments imported by your company.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Mr. Harbie Fletcher

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Your written reply should be directed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink, appearing to read "Doug D. Tolen", with a long horizontal flourish extending to the left.

Douglas D. Tolen  
Director, Florida District